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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,635	10/17/2003	Germaine Zocchi	F1584	1961

7590 05/23/2006  
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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/688,635	<b>Applicant(s)</b> ZOCCHI, GERMAINE	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 March 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 4 and 5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4 and 5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks filed 3/06/06. Claims 1-3 are cancelled. New claims 4 and 5 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/06/05 has been entered.

#### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leahy et al. (US 6,281,1920).

Leahy discloses a composition comprising mucin, Xanthan gum, buffering agents, tonicity agents, humectant, wetting agents (surface active agents) and preservatives; polyhexamethylene biguanide is a preservative; TETRONIC, PLURONIC and the polyethyleneoxide-polypropyleneoxide block copolymers are surfactants (column 8, lines 10-67); Xanthan gum is a

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viscosity agent and also anionic biopolymer. The contact lens formulation (Table XI, Example 10, formulation A and B) shows a formulation comprising 0.5% Tetronic, 15 ppm polyhexamethylene biguanide, 1% mucin for formula A and 2% mucin for formula B. Water is part of the composition. See also claims 1-25.

The 1% and 2% mucin meets the limitation of 0.1% to 5% generic anionic polymer or mucin (claims 1 and 2). The 0.5% Tetronic meets the limitation of 0.01 to 5 wt% surfactant recited in claim 3. Thus, Leahy discloses the instant composition. Antimicrobial cleaning is a future intended use of the composition and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the claimed invention is a composition and the prior art discloses compositions.

Furthermore, the instant composition and the composition of the prior art contain the antimicrobial agent, polyhexamethylene biguanide, both compositions must exhibit the same property and the property of a composition is not separable from the composition. The comprising language of the instant claims is open.

Leahy discloses the instant composition. Leahy differs in the amount of the biguanide. But, there is no demonstration in applicant's specification showing that the recited amount of the biguanide provides unexpected and unusual results. Generally, differences in amounts of the antimicrobial agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results or unusual results. "W[here] the general conditions of a claim are disclosed in the prior art, it is not

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inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation according to Leahy. One having ordinary skill in the art would have been motivated to use the appropriate amount of the antimicrobial agent, which in combination with the surfactant and the anionic biopolymer would produce a composition that have the desired antimicrobial properties.

4. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellis et al. (US 6,277,365) or Tetsuhisa et al. (JP 2000-109892, Computer translation).

Ellis discloses composition comprising 0.00001 to about 5 wt% of antimicrobial agent of which is polyhexamethylene biguanide hydrochloride; the composition also contains 0.015% xanthan gum; 0.015% GLUCQUAT 100 glycoside as surfactant in Example 1. Hyaluronic acid is disclosed in Example 3. However, in Test Solution 2, Ellis uses 15 ppm polyhexamethylene biguanide, 0.01% surfactant, and 0.3% xanthan gum. See also abstract; column 2, lines 40-45 and 54-67, columns 5 and 6 and claims 1-26. The 15 ppm is less than that required in the claims. The amount of the surfactant and the anionic biopolymer (hyaluronic acid or xanthan gum) meet the limitation of the amounts in the claims. Thus the difference between the claims and the prior art is in the amount of the biguanide antimicrobial agent. The composition contains water. Antimicrobial cleaning is a future intended use of the composition and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the claimed invention is a composition and the prior art discloses compositions.

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In the instant case, both the composition of the prior art and the composition of the claimed invention have the same ingredients and would therefore have the same antimicrobial properties from the biguanide and the surfactant. The comprising language of the claims is open. Generally, differences in amounts of the antimicrobial agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results or unusual results. “W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). And there is no demonstration in applicant’s specification showing that the recited amount of the biguanide provides unexpected and unusual results.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation according to Ellis. One having ordinary skill in the art would have been motivated to use the appropriate amount of the antimicrobial agent, which in combination with the surfactant and the anionic biopolymer would produce a composition that have the desired antimicrobial properties.

The Tetsuhisa prior art is of equal significance to claims 1 and 3 because Tetsuhisa discloses a composition that comprises 0.001-10 wt% chondroitin sulfate and/or hyaluronic and polyhexamethylene biguanide or salt thereof (abstract). The concentration of the biguanide or ammonium chloride derivative is 0.00001-0.1% (claims 1-5) and specifically discloses that the preferred concentration of the biguanide is from 0.00001-0.001% (see detailed description section at page 3, which concentration differs from the claimed concentration. The composition also contains surfactants (claim 6) and the amount of the surfactant is from 0.1-5%, and preferably

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0.01-10% (page 3 of detailed description section), and this meets the limitation of the claimed amount. The composition contains water.

Thus, Tetsuhisa discloses the claimed composition and the difference between the claims and the prior art is in the amount of the biguanide antimicrobial agent. Antimicrobial cleaning is a future intended use of the composition and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the claimed invention is a composition and the prior art discloses compositions.

In the instant case, both the composition of the prior art and the composition of the claimed invention have the same ingredients and would therefore have the same antimicrobial properties from the biguanide and the surfactant. Generally, differences in amounts of the antimicrobial agent will not support the patentability of the subject matter encompassed by the prior art unless there is evidence indicating such amount provides unexpected results or unusual results.

“W[here] the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). And there is no demonstration in applicant’s specification showing that the recited amount of the biguanide provides unexpected and unusual results.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the formulation according to Tetsuhisa. One having ordinary skill in the art would have been motivated to use the appropriate amount of the antimicrobial agent,

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which in combination with the surfactant and the anionic biopolymer would produce a composition that have the desired antimicrobial properties.

### ***Double Patenting***

5. The nonstatutory double patenting rejection is based on a judicially-created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 4 and 5 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No. 6,479,044.

Although the conflicting claims are not identical, they are not patentably distinct from each other because issued claim 1 comprises anionic surfactant, polyhexamethylene biguanide, non-anionic surfactant, fragrance and water, and the instant claim 1 contains anionic surfactant, water and polyhexamethylene biguanide. While issued claim 1 is not identical with instant claim 1, instant claims 4 and 5 taken as a whole represent obvious variation of the issued claims 1 and 2.

7. Claims 4 and 5 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 3 of copending



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Application No. 10/224,692. Although the conflicting claims are not identical, they are not patentably-distinct from each other because anionic biopolymer of examined claim 4 includes anionic surfactant species of the copending application and the polyhexamethylene biguanide is the same in both the examined and copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

According to MPEP 804 1B states “the “provisional” double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that “provisional” double patenting rejection is the only rejection remaining in one of the applications. If the “provisional” double patenting rejection in one application is the only rejection remaining in that application, the examiner should then withdraw that rejection and permit the application to issue as a patent, thereby converting the “provisional” double patenting rejection in the other application(s) into a double patenting rejection at the time the one application issues as a patent.

If the “provisional” double patenting rejections in both applications are the only rejections remaining in those applications, the examiner should then withdraw that rejection in one of the applications (e.g., the application with the earlier filing date) and permit the application to issue as a patent. The examiner should maintain the double patenting rejection in the other application as a “provisional” double patenting rejection, which will be converted into a double patenting rejection when the one application issues as a patent.”

#### ***Response to Arguments***

8. Applicant's arguments filed 3/6/06 have been fully considered but they are not persuasive.

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A). Regarding applicant's question about intended use, it is respectfully noted that antimicrobial cleaning is an intended use of the composition and a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In this case, the claimed invention is a composition and the prior art discloses compositions.

B). Regarding applicant's question about demonstration of unexpected result, it is respectfully noted that when the difference between the claimed composition and the composition of the prior art is in the amounts of the components, then a showing of factual evidence providing unexpected result of the claimed composition over the prior art would point to patentable distinction over the prior art on the basis of the amounts. This does not contradict the position that products/compositions having the same components, and are therefore the same cannot have mutually exclusive properties/functions and the intended use of these compositions would be the same. See MPEP 2106 [R-3] II C.

C). Regarding the exclusionary language of the new claims, it is respectfully noted that the comprising language is open.

D). Applicant provided no argument regarding the obviousness double patenting rejection and a response is thus not needed. The rejection is maintained.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tsao Fu-Pao (US 5,858,996) discloses ophthalmic composition comprising mixture of polyhexamethylene biguanide and hyaluronic acid among others (column 3, lines 52, 61 and 62 and claim 5. Jampani et al. (US 5,980,925) discloses a wash solution comprising hyaluronic acid and polyhexamethylene biguanide (column 3, line 2; column 5, line 11; column 4, line 62); the

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antimicrobial agent is present in amounts of 0.01 to 10%, preferably 0.01 to 5% and more preferably 0.1 to about 2% (column 3, lines 43-45). Policicchio et al. (US 6,910,823 B2) discloses cleaning composition (abstract).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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